sybron dental specialties

K093341

Section III - 510(k) Summary of Safety and Effectiveness

APR - 5 2010

Submitter:

Sybron Dental Specialties, Inc.
1717 West Collins Drive
Orange, CA 92656
Claudia Ortiz - Contact Person
Phone number: 714.516.7981
Fax number: 714.516.7488

Date Summary Prepared: October 19, 2009

Device Name:

- Trade Name – ***KaVo Century 105C***
- Common Name – Dental Handpiece and Accessories
- Classification Name - Handpiece, Air-powered, Dental, per 21 CFR 872.4200

Devices for Which Substantial Equivalence is Claimed:

- Kaltenbach & Voigt GmbH, *SUPERtorque Air-Driven Highspeed Handpieces (K073478)*

Device Description:

The *Century 105C Handpieces* are dental instruments for use by a trained professional in general dentistry. The handpieces are powered by pneumatic pressure on a rotor with roller bearings. The devices are re-usable and ergonomically shaped, and can be sterilized by the steam autoclave method.

Intended Use of the Device:

The *Century 105C Handpieces* are intended for the removal of carious material, cavities and crown preparations, removal of fillings, and processing of tooth and restoration surfaces. They are designed for use by a trained professional in the field of general dentistry.

Substantial Equivalence:

The *Century 105C Handpieces* are substantially equivalent to other legally marketed devices in the United States. The intended use of the devices is identical to that of the predicate. The *Century 105C Handpieces* are substantially equivalent in design, application and function to the *SUPERtroque Air-Driven Highspeed Handpieces* marketed by Kaltenbach & Voigt GmbH.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Claudia Ortiz
Compliance Director & Regulatory Affairs & Quality Assurance
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

APR - 5 2010

Re: K093341
Trade/Device Name: Century 105C
Regulation Number: 21CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: March 26, 2010
Received: March 30, 2010

Dear Ms. Ortiz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section I – Indications for Use

Indications for Use

510(k) Number (if known):

Device Name: Century 105C

Indications for Use:
The *Century 105C Handpieces* are intended for the removal of carious material, cavities and crown preparations, removal of fillings, and processing of tooth and restoration surfaces. They are designed for use by a trained professional in the field of general dentistry.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Kevin Mulloy for MSR
(Division Sign-Off) ~~Concurrence of~~ CDRH, Office of Device Evaluation (ODE)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093341